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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------|----------------------|---------------------|------------------|
| 09/691,817 | 10/18/2000 | Menno Kalmann | 19459-002200US | 5259 |
| 22470 7 | 7590 11/19/2003 | | EXAM | INER |
| HAYNES BEFFEL & WOLFELD LLP P O BOX 366 | | | ISABELLA, DAVID J | |
| HALF MOON BAY, CA 94019 | | | ART UNIT | PAPER NUMBER |
| | • | | 3738 | |

DATE MAILED: 11/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| • | | | | | | | |
|---|--|---|--|-----------|--|--|--|
| | | Application No. | Applicant(s) | | | | |
| Office Action Summary | | 09/691,817 | KALMANN ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | DAVID J ISABELLA | 3738 | | | | |
| Period fo | The MAILING DATE of this communication apported by the second section apport | pears on the cover sheet w | th the correspondence address | | | | |
| THE - Exte after - If the - If NC - Failu - Any | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a repl period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a r y within the statutory minimum of thin will apply and will expire SIX (6) MON o, cause the application to become AE | eply be timely filed ty (30) days will be considered timely. ITHS from the mailing date of this communication BANDONED (35 U.S.C. § 133). | 1. | | | |
| 1)⊠ | Responsive to communication(s) filed on 30 A | pril 2003. | | | | | |
| 2a)⊠ | This action is FINAL . 2b)☐ This | action is non-final. | | | | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposit | ion of Claims | | | | | | |
| 5)⊠ 6)⊠ 7)□ | ✓ Claim(s) 1-54 is/are pending in the application. 4a) Of the above claim(s) 46-54 is/are withdrawn from consideration. ✓ Claim(s) 1-20 is/are allowed. ✓ Claim(s) 21-45 is/are rejected. ☐ Claim(s) is/are objected to. ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| • | ion Papers | | | | | | |
| | The specification is objected to by the Examine | ar | | | | | |
| • | The drawing(s) filed on is/are: a) acc | | by the Examiner. | | | | |
| , | Applicant may not request that any objection to the | | | | | | |
| | Replacement drawing sheet(s) including the correct | | | d). | | | |
| 11) | The oath or declaration is objected to by the Ex | xaminer. Note the attache | d Office Action or form PTO-152. | | | | |
| Priority (| under 35 U.S.C. §§ 119 and 120 | | | | | | |
| * (3) / x s s s s s s s s s s s s s s s s s s | Acknowledgment is made of a claim for foreig All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Burea See the attached detailed Office action for a list Acknowledgment is made of a claim for domest ince a specific reference was included in the first CFR 1.78. Acknowledgment is made of a claim for domest deference was included in the first sentence of the foreign was included in the first sentence of the first was included in the first sentence of the first was included in the first sentence of the first was included in the first sentence of the first was included in the first sentence of the first was included in th | ts have been received. Its have been received in A Inity documents have been In (PCT Rule 17.2(a)). In of the certified copies not It priority under 35 U.S.C. Its sentence of the specific Its priority under 35 U.S.C. Its priority under 35 U.S.C. | application No I received in this National Stage received. § 119(e) (to a provisional application or in an Application Data Sheen received. §§ 120 and/or 121 since a specific | eet. C | | | |
| Attachmen | nt(s) | | | | | | |
| 1) Notice 2) Notice | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) _ | 5) 🔲 Notice of I | Summary (PTO-413) Paper No(s) nformal Patent Application (PTO-152) | | | | |

Art Unit: 3738

Election/Restrictions

Newly submitted claims 46-54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method of claims 46-54 are directed to a method for lining a section of a blood vessels whereas claims 1-45 are directed for replacing a section of a blood vessel inner layer. The newly presented claims fail to require the removal of a section of the inner layer of the blood vessel.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46-54 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-45 are rejected under 35 U.S.C. 102(e) as being aniticipated by Plaia et al (5571169).

Application/Control Number: 09/691,817

Art Unit: 3738

Page 3

Plaia, et al discloses a method for replacaing a section of a blood vessel inner layer comprising the steps of forming an incision into the blood vessel. Removing a section of the inner layer of the vessel through the incision. The removal of the predetermined section of the inner layer will leave the unselected portions intact. The unselected portion of the inner layer adjacent the radial or beveled cut is construed to be at least one end flap. Once the selected portion of the inner layer is removed, Plaia et al provides an artificial blood vessel inner layer comprising a diameter arranging element at one end thereof capable of creating an expandable end. The artificial vessels is then inserted into the blood vessel through the incision and positioned adjacent the blood vessel inner layer. The expandable end contains a diameter arranging element for retaining the artificial vessel to the natural vessel. See column 6, lines 55+, column 7, lines 30+, column 12, lines 10+ and 58+ and column 13, lines 10+.

Claim 22, see column 12, lines 12+.

Claim 23, see column 12, lines 6+.

Claim 29, see column 12, lines 12+.

Claim 32, see column 7, lines 10+.

Claim 33, see column 7, lines 10+.

Claims 34-41,45, see column 13, lines 49+.

Claim 42, see column 14, lines 39+.

Claims 43 and 44, see column 14, lines 58+ and column 15, lines 1+.

Claim Rejections - 35 USC § 103

Application/Control Number: 09/691,817

Art Unit: 3738

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plaia, et al. as applied to claim 21 above, and further in view of Lentz (5522881).

Plaia, et al discloses that the graft may be reinforced wtih rings and spirals. The reinforcement may be incorporated into the graft at one or both ends. Moreover, Plaia, et al discloses that the helical reinforcement maybe embedded in the graft or could be placed internally or externally of the graft itself. Plaia, et al discloses the reinforcement to be made of thermoplastic material. Lentz teaches a stent graft combination with a stent placed in the folded over portion of the graft (figure 4). Since Plaia, et al is not specific as to how the stent is placed on the graft, Lentz teaches one such manner for placement of the stent to the graft. Note, Lentz teaches that the stent can be made from any biocompatible materials including stainless steel, memory metal and thermoplastics (see column 3, lines 30+). To place the stent of Plaia, et al within the folds of the graft so as to ensure proper positioning of the stent with respect to the end portions of the graft would have been obvious from the teachings of Lentz.

The use of any equivalent materials including metal, memory metal or thermoplastic as the material for the ring would have been obvious to one with ordinary skill in the art as being dependent on design and engineering considerations of known equivalents.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are most in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

Application/Control Number: 09/691,817

Art Unit: 3738

Page 6

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DAVID J ISABELLA Primary Examiner Art Unit 3738

Dji 11/17/03